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In the Claims

but G9 *D1* 20. (Twice Amended) A composition for increasing the level of LIPG polypeptide in a patient comprising an LIPG polypeptide.

D2 80. (Amended) A composition according to Claim 79 wherein said aqueous buffer is selected from the group consisting of: Tris buffer; phosphate buffer; and HEPES buffer.

REMARKS

Reconsideration of the allowability of the present application in view of the above amendments and the following remarks is requested respectfully.

Status of the Claims

Amendments of an editorial nature have been made to Claims 20 and 80. No claims have been added or canceled. Claims 1, 7, 8, 10, 11, 13 to 16, 19, 21 to 25, 28 to 32, 34, 35, 37, 39 to 41, 43 to 47, 49 to 53, 55 to 59, 63 to 65, and 73 have been withdrawn as being drawn to a non-elected invention. While the Examiner noted in his Action that Claims 74 to 76 were withdrawn, the Examiner's Action addressed, nevertheless, such claims. The pending elected claims are Claims 20, 66 to 72, and 74 to 84.

Summary of the Invention

Applicants have developed a composition for increasing the level of LIPG polypeptide in a patient. The composition comprises LIPG polypeptide.

Traversal of the Examiner's § 102(b) Rejection of Claims 20, 66 to 72, and 74 to 76

Claims 20, 66 to 72, and 74 to 76 were rejected under §102(b) as being

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anticipated by Cooper et al., GenBank Database, Accession No. P 11602 (1989).

Applicants traverse respectfully the Examiner's rejection. For a reference to anticipate a claim, the reference must teach each and every element of the claimed invention. MPEP §706.02. Independent Claim 20, from which Claims 66 to 72 and 74 to 76 depend, recites that the composition comprises an LIPG polypeptide. LIPG polypeptide is defined in the application at page 30, lines 4 to 10, as a polypeptide encoded by the LIPG gene or any analogue, fragment, derivative, or mutant which is derived from such a polypeptide. Cooper et al. discloses a lipoprotein lipase precursor polypeptide which is encoded by the avian lipoprotein lipase gene. Cooper et al. does not disclose a polypeptide encoded by the LIPG gene or an analogue, fragment, derivative, or mutant derived from such a polypeptide.

Given the above, applicants request respectfully that the Examiner's §102(b) rejection of Claims 20, 66 to 72, and 74 to 76 as being anticipated by the disclosure of Cooper et al. be withdrawn.

Traversal of the Examiner's Rejection of Claims 20, 66 to 72, and 77 to 84 under the Enablement Requirement of §112, First Paragraph
Claims 20, 66 to 72, and 77 to 84 were rejected under the enablement requirement of §112, first paragraph. The Examiner based his rejection on his belief that: (A) LIPG polypeptide could be any triacylglycerol lipase; and (B) insufficient guidance exists in the application with respect to any LIPG polypeptide other than those of SEQ ID NOS: 6, 8, and 10.

Applicants traverse respectfully the Examiner's rejection.

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In the first instance, applicants note that it is not true that LIPG polypeptide could be any triacylglycerol lipase. As stated at page 30, lines 4 to 10, of the application, LIPG polypeptide is a polypeptide encoded by the LIPG gene or a derivative of such a polypeptide which retains at least one biological property thereof. The sequence of the complete open reading frame of the LIPG gene is disclosed in the application at SEQ ID NO: 7.

One of skill in the art, with knowledge of the LIPG gene, would be enabled to make and use LIPG polypeptides other than those of SEQ ID NOS: 6, 8, and 10. Regions which confer LIPG polypeptide biological activities include, for example, the 39 kD catalytic domain described at page 35, lines 24 to 28, of the application and the various regions discussed at page 26 of the application. One of skill in the art, upon reading the application, would be able, therefore, to modify, for instance, a portion of SEQ ID NO: 6 outside of the 39 kD catalytic domain and produce a polypeptide which is not a polypeptide of SEQ ID NO: 6 and which yet retains a biological property of LIPG polypeptide. Such a person skilled in the art would be enabled, therefore, to make and use an LIPG polypeptide other than those of SEQ ID NOS: 6, 8, and 10.

Given the above, applicants request respectfully that the Examiner's rejection of Claims 20, 66 to 72, and 77 to 84 under the enablement requirement of §112, first paragraph, be withdrawn.

Discussion of the Examiner's Rejection
of Claims 66 to 68 under the Enablement Requirement of §112, First Paragraph

Claims 66 to 68 were rejected under the enablement requirement of §112, first paragraph. According to the Examiner, applicants have not enabled a person of skill in the art to make and use a compound for enhancing the enzymatic activity of

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LIPG polypeptide or a compound for enhancing specifically the enzymatic activity of LIPG polypeptide with respect to LDL or VLDL cholesterol relative to HDL cholesterol and apo A-I.

Applicants traverse respectfully the Examiner's rejection. Pages 55 to 59 and Example 8 of the application teach one of skill in the art how to screen for such enhancer molecules. Pages 71 and 72 teach one of skill in the art how to use such enhancer molecules. One of skill in the art would, therefore, upon reviewing the present application, know how to identify and use such enhancer molecules.

Given the above, applicants request respectfully that the Examiner's rejection of Claims 66 to 68 under the enablement requirement of §112 be withdrawn.

Traversal of the Examiner's Rejection of
Claims 74 to 76 under the Enablement Requirement of §112, First Paragraph

Claims 74 to 76 were rejected under the enablement requirement of §112, first paragraph. According to the Examiner, applicants have not enabled the full scope of the invention defined in Claims 74 to 76.

Applicants traverse respectfully the Examiner's rejection. The Examiner's attention is directed to page 30, lines 4 to 10, of the application in which LIPG polypeptide is defined as being a polypeptide encoded by the LIPG gene or a derivative of such a polypeptide which retains at least one biological property thereof. As stated above in the arguments for traversing the Examiner's rejection of Claims 20, 66 to 72, and 77 to 84 under the enablement requirement of §112, one skilled in the art would be enabled to make and use variations of polypeptides of SEQ ID NOS: 6, 8, and 10 which retain at least one biological property thereof. One skilled in the art is enabled to make and use variations, therefore, of SEQ ID

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NOS: 6, 8, and 10 which are encompassed by Claims 74 to 77.

Discussion of the Examiner's Rejections under §112, Second Paragraph

The Examiner's rejection of Claim 20, 66 to 72, and 74 to 84 as being indefinite in the use of the term "LIPG" is traversed respectfully. Applicants note that the term "LIPG" is not indefinite since LIPG polypeptide is defined at page 30, lines 4 to 10, of the application.

The Examiner's rejection of Claims 20, 77 and 84 as being indefinite for referring to a composition for pharmaceutical use is traversed respectfully. Applicants note that the disclosure at pages 25 to 28 and 59 to 63 of the application describes such pharmaceutical compositions, uses thereof, compounds contained therein, and dosage amounts for the compounds contained therein.

The Examiner's rejection of Claim 80 as being indefinite has been overcome by the above Amendment.

The Examiner's rejection of Claim 20 as being indefinite in the use of the term "pharmaceutical" has been overcome by the above amendment to Claim 20 in which the term "pharmaceutical" has been deleted.

Discussion of Claims 74 to 76

In his Action, the Examiner failed to address applicants' traversal of the Examiner's April 24, 2001 Requirement for Restriction in which applicants traversed the Examiner's Requirement with respect to Claims 20, 66 to 72 and 77 to 84 (the Group VIII claims) and Claims 74 to 76. Applicants note that while the Examiner stated that Claims 74 to 76 were "withdrawn", the Examiner's Action

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addressed, nevertheless, Claims 74 to 76.

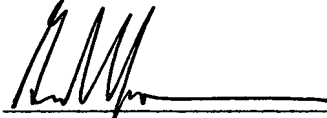
Conclusion

For the reasons expressed above, applicants request respectfully that the Examiner reconsider and withdraw the rejections under §§102 and 112.

Attached hereto is a marked-up version of the changes made to the application by the current amendment. The attached version is captioned "Version with Markings to Show Changes Made."

In view of the foregoing amendment and remarks, an early and favorable action is requested respectfully.

Respectfully submitted,



Gene J. Yao, Esquire
Reg. No. 47,193
Attorney for Applicants

Synnestvedt & Lechner LLP
Suite 2600 Aramark Tower
1101 Market Street
Philadelphia, PA 19107-2950
(215) 923-4466

VERSION WITH MARKINGS TO SHOW CHANGES MADE

20. (Twice Amended) A [pharmaceutical] composition for increasing the level of LIPG polypeptide in a patient comprising an LIPG polypeptide.

80. (Amended) A composition according to Claim [78] 79 wherein said [biologically-compatible solution] aqueous buffer is selected from the group consisting of: Tris buffer; [phosphpate] phosphate buffer; and HEPES buffer.